

CLAIMS

- 1) A stable pharmaceutical solid or semisolid dispersion comprising at least one oxidation-susceptible and poorly water-soluble drug as active ingredient, a hydrophilic carrier, a water-soluble vitamin E derivative as antioxidant agent and optionally other excipients.
- 2) A stable pharmaceutical solid or semisolid dispersion according to claim 1 wherein the active ingredient incorporates at least one amine, aldehyde or hydroxy functional group or has at least a double or triple bond in their chemical structure and has an intrinsic solubility in water of less than about 500 µg/mL.
- 3) A stable pharmaceutical solid or semisolid dispersion according to claim 2 wherein the active ingredient has an intrinsic solubility of less than about 200 µg/mL.
- 4) A stable pharmaceutical solid or semisolid dispersion according to claim 1 wherein the active ingredient is selected from the group consisting of posaconazole, tocotrienate, nitrendipine, tiagabine, hydrocortisone/cortisol, tacrolimus, testosterone, metaclozepam, morphine, metamethasone valerate, captopril, nicotine, dronabinol, formestane, atamestane and exemestane.
- 5) A stable pharmaceutical solid or semisolid dispersion according to claim 1 wherein the active ingredient is exemestane.
- 6) A stable pharmaceutical solid or semisolid dispersion according to claim 1 wherein the amount of active ingredient is in the range of from about 25% to 1%.
- 7) A stable pharmaceutical solid or semisolid dispersion according to claim 6 wherein the amount of active ingredient is from 15% to 2%.
- 8) A stable pharmaceutical solid or semisolid dispersion according to claim 1 wherein the antioxidant agent is d-alpha-tocopherol polyethylene glycol ester.

9) A stable pharmaceutical solid or semisolid dispersion according to claim 8 wherein the oxidant agent is d-alpha-tocopherol polyethylene glycol 1000 succinate.

10) A stable pharmaceutical solid or semisolid dispersion according to claim 1 wherein
5 the antioxidant agent is used in the range from 1% to 0.01% w/w.

11) A stable pharmaceutical solid or semisolid dispersion according to claim 1 wherein the antioxidant agent is used in the range from 0.5% to 0.02% w/w.

10 12) A stable pharmaceutical solid or semisolid dispersion according to claim 1 wherein the hydrophilic carrier is in an amount from 20% to 95% w/w

13) A stable pharmaceutical solid or semisolid dispersion according to claim 12 wherein the hydrophilic carrier is in an amount from 90% to 70% w/w.

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14) A method of inhibiting oxidative degradation of pharmaceutical formulations containing at least one oxidation-susceptible and poorly water-soluble drug as active ingredient which method comprises adding to the formulation a low amount of a water soluble vitamin E derivative as antioxidant agent.

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15) A process for preparing a stable solid or semisolid dispersion for oral administration of an oxidation -susceptible and poorly water-soluble drug which process comprises mixing the oxidation-susceptible and poorly water-soluble drug, the hydrophilic carrier and the water soluble vitamin E derivative, and melting the resultant mixture.

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